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EXAMINER	
WOITACH, JOSEPH T	
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1632	16

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/559,622	Applicant(s) RANGANATHAN ET AL.	
	Examiner Joseph Woitach	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *1-8,10 and 12-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,11 and 20-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *13*
4)☐ Interview Summary (PTO-413) Paper No(s). _____
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other

DETAILED ACTION

This application filed April 27, 2000, claims benefit to provisional application 60/131,149, filed April 27, 1999.

Applicants' amendment filed April 30, 2002, paper number 15, has been received and entered. The specification has been amended. Claims 9 and 11 have been amended. Claims 22-29 have been added. Claims 1-29 are pending.

Election/Restriction

Applicants note that claims 20 and 21 were not included in any specific group set forth in restriction requirement, paper number 9, and that they are encompassed in the elected invention as drawn to a method for identifying a compound that modulates the biological activity of a serotonin-gated anion channel. Upon review of the restriction requirement and the claims, Examiner agrees that claims 20 and 21 should be included in the examination of elected group V. Claims 1-29 are pending. Applicant's election without traverse of group V, claims 9 , 11, 20 and 21 in Paper No. 11 is acknowledged. Additionally, newly added claims 22-29 are dependent on claims 9 and 11, and are drawn to the elected invention. Claims 1-8, 10 and 12-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim. Claims 9, 11 and 20-29 are currently under examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The objection to the disclosure for the lack of a Brief Description of the Figures under 37 CFR 1.74 is withdrawn.

The amendments to the specification have obviated the basis of the objection.

Claim Objections

Claims 22 and 23 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is noted that claims 22 and 23 recite hybridization conditions which would be considered to be more stringent than those recited in claims 9 and 11, however, this does not specifically provide a further limitation to the independent claims. Examiner would concede that it may be that the different sequences would be identified under particular hybridization conditions, however the method encompassed by claims 22 and 23 is not

further limiting rather it is directed to a different method encompassing different hybridization conditions.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Newly amended claims 9 and 11, and newly added claims 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The final Written Description Examination guidelines that were published on January 5, 2001 (66 FR 1099; available at http://www.uspto.gov/web/menu/current.html).

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116. In the instant case, the claims are drawn to use of a purified polynucleotide sequence which

hybridizes under particular conditions recited in the claims and encodes an anion channel which is used in a method for testing the properties of an unknown compound for affects on said anion channel. The specification teaches that SEQ ID NO: 2 encodes mod-1 which is responsible for serotonin-gated chloride activity. Mutants of SEQ ID NO: 2 are taught however, they are demonstrated to be defective and non-functional when expressed in cells or in transgenic C. elegans. The instantly claimed method requires that a functional serotonin-gated anion channel be present in order to assay affects on said receptor, however the specification fails to provide any clear and specific guidance to what these receptors would be, and more specifically, what specific sequences would be used besides the functional sequence as set forth in SEQ ID NO: 2. The specification fails to adequately describe any other serotonin-gated sequences besides that set forth in SEQ ID NO: 2 which would meet the functional limitations necessary for use in the practice of the method as claimed. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998). In the instant case, the specification teaches that general hybridization conditions can be used to identify related sequences (see for example

page 34). It is noted that the methodology is described for use in identifying related serotonin-gated anion channels, not in methods for using said sequences to define properties of unknown compounds. The specification and the art of record provide a functional analysis of the serotonin-gated anion channel set forth in SEQ ID NO: 2, however the specification fails to describe the relevant identifying characteristics of any of the specific nucleic acid sequences which would be identified with the general methods of hybridization. Further, the only variants of SEQ ID NO: 2 specifically taught encompass sequences which lack the activity which would be assayed in the instantly claimed methods. The skilled artisan cannot envision all the possible variant nucleic acid sequences which would hybridize but do not encode a serotonin-gated anion channel, or sequences which are related but have no assayable activity which can be used in the instantly claimed method. Given the functional sequence set forth in SEQ ID NO: 2, the skilled artisan would not know what specific changes one could make to this sequence which would result in a purified polynucleotide sequence which would be meet the functional requirement for use in the instantly claimed method, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

Applicants attention is drawn to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein it was stated:

In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers,* 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what it achieves as a result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. In the instant case, only SEQ ID NO: 2 provides the polynucleotide sequence necessary for use in and practice of the instantly claimed method. While other variations of this sequence can be identified with the hybridization conditions set forth in the claims, the specification lacks a clear description of a serotonin-gated anion channel which would distinguish any polynucleotide sequence which hybridizes to SEQ ID NO: 2 as a polynucleotide which would be functional in the instantly claimed methods.

Therefore, only SEQ ID NO: 2 meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 11, 22, 23 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

First, the amendments to the claims have obviated the basis of the specific rejections previously set forth, and the rejections as they apply to the previous rejections is withdrawn.

Newly amended claims 9 and 11 and newly added claims 22 and 23 are unclear and confusing in the recitation of "a cell comprising a serotonin-gated anion channel encoded by a purified nucleic acid sequence" because it is unclear if the nucleic acid sequence is actually contained in the cell and not purified, or how the purified nucleic acid would be used to generate the protein of interest, and be provided to the cell for the claimed assay. Upon review of the present specification, it is unclear how a purified nucleic acid sequence would be used in a cell based assay, absent the sequence already being present in the cell or providing a step wherein the nucleic acid sequence is delivered into the cell. Additionally, it is not clear if the instant claims read on the cell containing and expressing the endogenous gene encoding a serotonin-gated anion

channel. Amending the claim to clearly indicate how the nucleic acid provides the desired protein to the cell for use in the assay would obviate the basis of the rejection.

Claims 22 and 23 are confusing because they fail to further limit independent claims 9 and 11. As noted above in the claim objections, the method of hybridization does not comprise an additional step which would further limit claims 9 and 11.

Claims 26 and 29 are unclear in the recitation of "comprises chloride ions" because it is unclear how this further limits claims 9 and 11. The anion channel receptor set forth in SEQ ID NO: 2 is a chloride ion channel, so it would inherently provide a change in the chloride gradient. It is unclear how claims 26 and 29 further limit claims 9 and 11 because the ability to conduct chloride is an inherent property of SEQ ID NO: 2. Alternatively, claims 9 and 11 are confusing, because the receptor encompassed by the claims appear to encompass properties which are different from those disclosed in the present specification and the art of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9 and 11 stand rejected and newly added claims 22-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Scrogin *et al.* (IDS ref. Am. J. Physiol, Dec 1998).

Claims 9 and 11 stand rejected and newly added claims 22-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Ali *et al.* (IDS reference J. Physiol. May 1998).

Claims 9 and 11 stand rejected and newly added claims 22-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Montigny *et al.* (IDS reference Science, 1978).

Claims 9 and 11 stand rejected and newly added claims 22-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Garner *et al.* (IDS reference Eur. J. Pharm., 1993).

Applicants note that claims 9 and 11 have been amended to recite specific sequences which are identified by hybridization conditions set forth in the claims, and argue that none of the references specifically teach nucleic acid sequences which are related to SEQ ID NO: 2. See Applicants amendment, pages 12-13. Applicants' arguments have been fully considered but not found persuasive.

As noted above in the basis of the rejection made under 35 USC 112, second paragraph, the nature of the polynucleotide sequence which encodes a serotonin-gated anion channel is unclear and can reasonably be interpreted to encompass the endogenous sequence comprised in the genome of a cell. Newly added claims recite limitations which would be inherent to the property of the compound being tested and to the specific affect of said compound on the receptor. Each of the limitations in the newly added claims would be inherent to a cell which expresses a serotonin-gated anion channel. Further it is noted that case law states that the office

does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989). In the instant case, as set forth in detail in the previous office action, each Scrogin *et al.*, Ali *et al.*, Montigny *et al.* and Garner *et al.* disclose a cell which expresses a serotonin-gated anion channel and methods of assaying the effectiveness of compounds on the activity of said channel. Examiner concedes that the references do not teach the specific hybridization conditions set forth in the claim, nor the specific sequences which encode the serotonin-gated anion channel assayed in the references. However, given that the specification teaches that the hybridization conditions specifically taught can be used to identify related sequences encoding serotonin-gated anion channels, there is no evidence of record which would indicate that the sequences comprised in the cells taught in each Scrogin *et al.*, Ali *et al.*, Montigny *et al.* and Garner *et al.* would not hybridize under the conditions set forth in the claim. Therefore, for the reasons above and of record, it is maintained that the claims are anticipated by each Scrogin *et al.*, Ali *et al.*, Montigny *et al.* and Garner *et al.*

Claims 20 and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Hamdan *et al.* (J Neuro, April 1999).

Claims 20 and 21 are drawn to identifying a compound that modulates activity of a serotonin-gated anion channel comprising exposing a nematode to a test compound and assessing the change in locomotion rate or swimming activity of said nematode. It is noted that SEQ ID NO: 2 encodes mod-1 a serotonin-gated anion channel which was isolated from *C. elegans*. Hamdan *et al.* teach the characterization of novel serotonin receptors isolated from the nematode *C. elegans*. Hamdan *et al.* teach that the serotonin receptor is associated with multiple observable phenotypes including affects on neurosecretory motor neurons which affect locomotion (page 1372, first paragraph). Hamdan *et al.* teach that the splice variants are expressed in *C. elegans* (summarized in figure 8) and characterize the effect of multiple compounds to determine the affects of said compounds in the functional characterization of the cloned receptors. Therefore, the teachings of Hamdan *et al.* anticipate the claims.

Claims 9, 11 and 20-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Horvitz *et al.* (Science May 1982).

Claims 20 and 21 are summarized above. Horvitz *et al.* provide a general review of the nervous system in *C. elegans* and describe the implication of observable affects elicited through the exogenous application of serotonin to a population of *C. elegans* (page 1013). Among the affects observed upon delivery of serotonin is the decreased locomotion (page 1013, bottom of

first column). Other compounds are also applied to the *C. elegans*, and result in poor movement and *C. elegans* exhibiting a kinked shape (pages 1013-14, starting at the top of third column). The characterization of *C. elegans* and in particular the affect of serotonin taught in Horvitz *et al.* meet all the limitations set forth in the claims. Therefore, the teachings of Horvitz *et al.* anticipate the claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach

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